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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08,538,709	10-03-1995	DOUGLAS P. CERRETTI	2826-A	6869

22932 7590 05/17/2002

IMMUNEX CORPORATION
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SEATTLE, WA 98101

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/17/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/538,709

Applicant(s)

CERRETTI, DOUGLAS P.

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 29-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Action

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647, Regina M. DeBerry.

Status of Application, Amendments, and/or Claims

Prosecution is hereby reopened.

The amendment filed 26 February 2001 (Paper No. 17) has been entered in full. Claims 53-57 were entered. The Information Disclosure Statement filed 26 February 2001 (Paper No. 18) will not be entered because the document submitted is an application (08/393,462). The declaration under 37 C.F.R. 1.131 submitted 26 February 2001 (Paper No. 19) was entered.

Claims 29-57 are under consideration in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Matter of Record

In the declaration under 37 C.F.R. 1.131, Appendix E, there is a discrepancy between mouse LERK-6 listed in the amino acid comparison (pages 0040-0045) and mouse LERK-6 listed as SEQ ID NO:2. In Appendix E, Applicant states that the DNA encoding the first 5 amino acids shown in Appendix E is derived from the sequencing vector, as indicated by the mark between the fifth amino acid (Arg) and the sixth amino acid (Ala). The open-reading frame within this sequence in Appendix E (and within SEQ

ID NO:1) encodes a protein of 184 amino acids beginning with the second Ala. However it appears that the open-reading frame for SEQ ID NO:1 and SEQ ID NO:2 listed in the Raw Sequence Listing starts with the first Ala. Clarification is required.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Rejections - 35 USC § 102

Claims 29-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Flanagan *et al.* in U.S. Patent Number 6,268,476 B1. The basis for this rejection was set forth at page 3 of the previous Office Action (Paper No. 16 26 September 2000).

The instant claims are generally drawn to isolated DNA encoding a LERK-6 polypeptide that binds hek/elk, wherein said polypeptide comprises amino acids 1 to 184 of SEQ ID NO:2, amino acids 1 to 145 of SEQ ID NO:2 and amino acids 1 to 134 of SEQ ID NO:2. The claims are also drawn to isolated DNA molecule wherein the DNA comprises nucleotides 1 to 552 of SEQ ID NO:1, nucleotides 1 to 435 of SEQ ID NO:1 and nucleotides 1 to 402 of SEQ ID NO:1, vector, host cell and process of making the LERK-6 polypeptide.

In U.S. Patent Number 6,268,476 B1, Flanagan *et al.* teach isolated nucleic acid molecules which are 100% identical to the following: amino acids 1 to 184 of SEQ ID NO:2, amino acids 1 to 145 of SEQ ID NO:2, amino acids 1 to 134 of SEQ ID NO:2, nucleotides 1 to 552 of SEQ ID NO:1, nucleotides 1 to 435 of SEQ ID NO:1 and nucleotides 1 to 402 of SEQ ID NO:1. Please see the attached sequence query (Appendix A and B). Flanagan *et al.* also teach vectors, host cells and methods of making recombinant proteins (column 9, line 48-column 10, line 36).

Applicant states (pages 2-3 Paper No. 17 26 February 2001) that Flanagan is not prior art with respect to the present claims. Applicant states that, "That is, even assuming *arguendo*, that Flanagan has an effective filing date under 35 USC 102(e) of September 19, 1994, this date is a mere two weeks prior to Applicant's effective filing date of October 5, 1994". Applicant also states, "In order to demonstrate that Applicant conceived and reduced to practice the invention claimed in the present invention prior to September 19, 1994, assuming *arguendo*, that Flanagan has an effective date of September 19, 1994, and thereby remove Flanagan as prior art against the present claims, Applicants submits herewith a Declaration under 37 CFR 1.131".

Applicant arguments have been fully considered but are not deemed persuasive for the following reasons. A declaration under 37 CFR 1.131 is not sufficient to overcome a 102(e) rejection where different inventors are claiming the same invention or obvious variants thereof. Applicant's attention is directed to 37 CFR 1.608(b).

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Conclusion

Claims 53-57 would be allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD

RMD
May 10, 2002

Elizabeth C. Kenna

ELIZABETH C. KENNA
PRIMARY EXAMINER